

C. Alternative Methods for Obtaining Antimicrobial Use Data

FDA is seeking public comment on alternative methods available to the Agency for obtaining additional data and information about the extent of antimicrobial drug use in food-producing animals. Specifically, the Agency is requesting public input on alternative methods for assessing antimicrobial use the Agency can employ within its existing authority that may further support the analysis of factors related to the development and spread of antimicrobial resistance in connection with the use of medically important antibiotics in food-producing animals.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

This advanced notice of proposed rulemaking is issued under section 512 of the FD&C Act (21 U.S.C. 360b) and under the authority of the Commissioner of Food and Drugs.

IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. U.S. General Accounting Office, "Antibiotic Resistance: Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals," GAO-11-801, Washington, DC, General Accounting Office, 2011 (<http://www.gao.gov/new.items/d11801.pdf>).

2. Guidance for Industry #209, entitled "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" (<http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>).

Dated: June 29, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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LIBRARY OF CONGRESS

Copyright Office

37 CFR Parts 201 and 210

[Docket No. 2012-7]

Mechanical and Digital Phonorecord Delivery Compulsory License

AGENCY: Copyright Office, Library of Congress.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Copyright Office of the Library of Congress is proposing to amend its regulations for reporting Monthly and Annual Statements of Account for the making and distribution of phonorecords under the compulsory license, 17 U.S.C. 115, to bring the regulations up to date to reflect recent and pending rate determinations by the Copyright Royalty Judges, which among other things provide new rates for limited downloads, interactive streaming and incidental digital phonorecord deliveries, and to harmonize these reporting requirements with the existing regulations for reporting the making and distribution of physical phonorecords, permanent downloads and ringtones.

DATES: Comments are due no later than September 25, 2012. Reply comments are due October 25, 2012.

ADDRESSES: The Copyright Office strongly prefers that comments be submitted electronically. A comment submission page is posted on the Copyright Office Web site at <http://www.copyright.gov/docs/section115/soa/comments/>. The Web site interface requires submitters to complete a form specifying name and other required information, and to upload comments as an attachment. To meet accessibility standards, all comments must be uploaded in a single file in either the Adobe Portable Document File (PDF) format that contains searchable, accessible text (not an image); Microsoft Word; WordPerfect; Rich Text Format (RTF); or ASCII text file format (not a scanned document). The maximum file size is 6 megabytes (MB). The name of the submitter and organization should appear on both the form and the face of the comments. All comments will be posted publicly on the Copyright Office Web site exactly as they are received, along with names and, if provided, organizations. If electronic submission of comments is not feasible, please contact the Copyright Office at (202) 707-XXXX for special instructions.

FOR FURTHER INFORMATION CONTACT: Tanya Sandros, Deputy General

Counsel, or Stephen Ruwe, Attorney Advisor, Office of the General Counsel, PO Box 70400, Washington, DC 20024-0400 Telephone: (202) 707-1673. Telefax: (202) 252-3423.

SUPPLEMENTARY INFORMATION:

Background

Section 115 of the Copyright Act provides a compulsory license for reproducing and distributing phonorecords of a musical work. The mechanical license limits the exclusive rights granted to copyright owners by enabling anyone to make a phonorecord of an eligible musical work for the purpose of distributing it to the public for private use.

The mechanical license may be used once phonorecords of a nondramatic musical work have been distributed to the public in the United States under the authority of the copyright owner. In order to legally use the mechanical license, the licensee has to comply with the requirements in the statute and pay a royalty fee to the copyright owner. The mechanical license has its limitations; it is only available to make and distribute phonorecords of a musical work and it does not allow the licensee to reproduce and distribute another's sound recording, or change the "basic melody or fundamental character of the work." 17 U.S.C. 115(a)(2).

The mechanical license was established in the 1909 Copyright Act as the first compulsory license in United States copyright law. Congress created the license because it wanted to make musical compositions available for public use, prevent monopoly, and at the same time ensure that compensation is provided to copyright owners. The first mechanical license was established in response to the 1908 Supreme Court holding in *White-Smith Music Publishing Co. v. Apollo Co.*, 209 U.S. 1 (1908). The Court decided that piano rolls were not considered 'copies' of a musical work because they did not contain a system of notation that could be read. Instead, the Court held they were merely mechanical reproductions made for the purpose of performing music. This decision prompted Congress to extend copyright protection to include the right to make mechanical devices which embody the musical work. H.R. Rep. No. 60-2222, at 9 (1909). However, Congress was concerned that extending the right of reproduction to include mechanical devices like piano rolls would enable a cartel of music publishers to exercise monopoly power over the recording of music to the possible detriment of the copyright owners of the musical work. To ensure a balance, Congress created

the first compulsory license in 1909 to allow anyone to “cover” (i.e. make a new recording of) the musical work once a copyright owner made or authorized a recording of his or her musical work, as long as the licensee adhered to the terms of the license and paid the established royalty to the copyright owner.

Whether to retain the compulsory license was a key issue during the discussions on the general revision of the copyright law in the 1960s. The outcome of this review was the decision to retain the license based on a finding that “a compulsory licensing system is still warranted as a condition for the rights of reproducing and distributing phonorecords of copyrighted music.” H.R. Rep. No. 83, at 66–67 (1967). In the Copyright Act of 1976, Congress reaffirmed the compulsory license and directed the Copyright Office to establish terms and regulations for the filing of Notices of Intention to Obtain a Compulsory License and for reporting Monthly and Annual Statements of Account. 17 U.S.C. 115(b)(1) and (c)(5). These regulations can now be found within 37 CFR 201.18 and 201.19.

Congress again amended the mechanical license in 1995 when Congress passed the Digital Performance Rights in Sound Recordings Act (“DPRA”). This Act amended section 115 to address the effects of new technology on copyrighted works. DPRA had two main purposes: (1) To ensure that recording artists and record companies will be protected as new technologies affect the way in which their creative works are used, and (2) to create fair and efficient licensing mechanisms that address the complex issues facing copyright owners and copyright users as a result of the rapid growth of digital audio services.

Specifically, DPRA amended the section 115 compulsory license to include the ability to distribute a phonorecord through digital transmission, i.e., as a “digital phonorecord delivery.” The Copyright Act defines a “digital phonorecord delivery” in relevant part as “each individual delivery of a phonorecord by digital transmission of a sound recording which results in a specifically identifiable reproduction by or for any transmission recipient of a phonorecord of that sound recording.” 17 U.S.C. 115(d).

Since passage of the Copyright Royalty and Distribution Reform Act of 2003, the rates and terms for making and distributing phonorecords under the compulsory license have been established by the Copyright Royalty Judges. On January 9, 2006 the

Copyright Royalty Judges published a Notice announcing commencement of a proceeding to determine rates and terms due under the compulsory license. The Copyright Royalty Judges concluded this proceeding in 2009. The new rates maintained a flat penny rate for the making and distribution of physical phonorecords, permanent digital downloads and ringtones. However, the 2009 determination adopting new rates for the section 115 compulsory license included a new definition for ringtones and it set forth more complex methods for calculating the royalty for limited downloads, interactive streaming, and incidental digital phonorecord deliveries, which included a multi-step process and specifications for five different types of services. *Final Determination of Rates and Terms of the Copyright Royalty Board*, 2006–3 CRB DPRA (74 FR 4510, January 26, 2009, amended 74 FR 6832, February 11, 2009). The Copyright Royalty Judges are also in the final stages of adopting new rates and terms for the next licensing term for these and other new services, including limited offerings, mixed service bundles, paid locker services and purchased content locker services. Proposed rule, *Adjustment of Determination of Compulsory License Rates for Mechanical and Digital Phonorecords*, 77 FR 29259, (May 17, 2012). The new proposed rates are based upon the same basic methodology adopted in the last rate setting proceeding.

The existing regulations addressing Statements of Account are designed to address flat penny rates, such as those that are still applicable for the making and distribution of physical phonorecords, permanent digital downloads and ringtones. However, the current regulations do not specifically accommodate the more complex methods for calculating the royalty for limited downloads, interactive streaming, incidental digital phonorecord deliveries, or the new services identified in the Copyright Royalty Judge’s May 17, 2012 Notice of Proposed Rulemaking. A group of industry stakeholders comprised of Recording Industry Association of America, Inc., National Music Publishers Association, Songwriters Guild of America, Digital Media Association, Music Reports, Inc., RightsFlow, Inc., and American Association of Independent Music (collectively “Stakeholders”) expressed their concern with this state of affairs. Following a number of meetings with the Copyright Office, the Stakeholders offered proposed solutions to a number

of issues for which there was general industry-wide agreement. (Letter from Stakeholders to Copyright Office, dated April 30, 2010).

In light of the changes to the rate structure for use of the license and the Stakeholders’ expressed concerns, the Office is initiating this public notice and comment proceeding to amend its regulations governing the filing of Statements of Account in order to incorporate specific reporting regulations for the making and distribution of these new digital phonorecord formats under the new rate structure established by the Copyright Royalty Judges for these configurations in the Final Determination of Rates and Terms of the Copyright Royalty Board, 2006–3 CRB DPRA, and the proposed new rates and terms for the next licensing period.

The Copyright Office is acting under the authority set forth in 17 U.S.C. 115(c)(5), which grants the Copyright Office authority to issue regulations regarding Statements of Account. “Each monthly payment shall be made under oath and shall comply with requirements that the Register of Copyrights shall prescribe by regulation. The Register shall also prescribe regulations under which detailed cumulative annual statements of account, certified by a certified public accountant, shall be filed for every compulsory license under this section. The regulations covering both the monthly and the annual statements of account shall prescribe the form, content, and manner of certification with respect to the number of records distributed.” 17 U.S.C. 115(c)(5).

Specifically, the Copyright Office proposes the creation of a new Part 210 in title 37 of the Code of Federal Regulations for the regulations governing use of the compulsory license. Subpart A will be reserved for regulations governing the filing of Notices of Intention to Use the Compulsory License. These regulations, currently in § 201.18, are to be incorporated into Subpart A once the Office concludes its ongoing rulemaking proceeding concerning the electronic submission of such notices with the Office. See 77 FR 31327 (May 25, 2012). Subparts B and C will contain Statement of Account provisions for reporting royalties for the making and distribution of phonorecords. The Statement of Account provisions in § 201.19 are currently based on the penny rate royalty formula for physical phonorecords and permanent digital phonorecord deliveries. As the a penny rate for this type of licensed activity continues under the existing and

proposed rates the Statement of Account provisions in § 201.19 are incorporated into proposed Subpart B of Part 210 with only minor amendments, as referenced herein. Subpart C, on the other hand, includes new proposed regulations modeled on the current regulations in § 201.19 and are designed to specifically accommodate the new rate structure for limited downloads, interactive streaming, incidental digital phonorecord deliveries, and the proposed new services. Adoption of regulatory amendments specific to the proposed rates and terms for limited offerings, mixed service bundles, music bundles, paid locker services and purchased content locker services set forth in proposed Subpart C are dependent upon final action by the Copyright Royalty Judges. Should the Copyright Royalty Judges not adopt the proposed rates and terms for these new services, alternative regulatory changes may be adopted in the final rules to cover these services.

In large part, the proposed regulations incorporate by reference the methodology adopted by the Copyright Royalty Judges in their 2009 determination and mirrored in the proposed regulations adopting new rates and terms for the upcoming licensing period. Nevertheless, the Office has identified a number of issues associated with the new rate structure that require careful consideration before adoption of final regulations. Prior to initiating this proceeding, the Office consulted with interested parties on these points for the purpose of understanding the extent of the issues and the need for specific regulations to address these points. Each of these points and proposed amendments to the regulations are discussed herein in light of these initial discussions. The Office seeks public comment on the proposed changes and whether additional changes are needed.

1. Issues Presented Involving Calculations of Royalties

A. Royalties for Public Performances of Musical Works That Are Applicable to the Licensed Activities

Calculation of the royalties for the making and distribution of limited DPDs, interactive streams, incidental DPDs and the proposed new services allows the licensee to deduct royalties due for public performances of musical works that are applicable to the licensed activities. 37 CFR 385.12(b)(2) and proposed 385.22(b)(2). The Office is aware that in some instances these values are unknown, and that the regulations need to address the appropriate method for accounting for

this unknown element in the Statements of Account. Preliminary input from the Stakeholders has indicated general agreement that when the amount of public performance royalties to be deducted pursuant to 37 CFR 385.12(b)(2) and proposed 385.22(b)(2) is not known (e.g., because neither a final nor an interim rate has yet been determined), a licensee may compute the public performance royalty based on a reasonable estimate of the expected final royalties made in accordance with U.S. Generally Accepted Accounting Principles (GAAP) and that the aggregate amount of public performance royalties then sought from the service by performance rights societies may be deducted from the royalties owed for use of the section 115 compulsory license.

The Office also observes that there may be cases in which there will be interim royalties and that therefore it is prudent to allow licensees to compute the public performance royalty based on the royalties that have been established on an interim basis. In addition, the Stakeholders generally agree that an adjustment to account for the determination of the service's aggregate final public performance royalties then would be made in an amended Annual Statement of Account for the year in which a service's aggregate final public performance royalty rate is determined.

In the past, the Copyright Office has applied GAAP when estimates are required to complete a formula under section 115. GAAP was first applied to the section 115 compulsory license in 1978 when the Office adopted its *Final Regulations of Compulsory License for Making and Distributing Phonorecords*, 45 FR 79038 (November 28, 1980). In taking this approach, the Office noted that Congress's intention was to have some assurance that record companies would not manipulate their statements when allowing an estimate to be made in the reserve calculation. "The Office believes that the statutory requirement for an annual CPA audit, coupled with our regulatory requirements including the application of 'generally accepted accounting principles' (GAAP) to the recognition of revenue from the sale of phonorecords, should go a long way toward assuring copyright owners payment of all monies to which they are entitled—that is, statutory royalties for all phonorecords shipped, minus phonorecords returned within a reasonable time-frame." 45 FR 79038. Additionally the regulations stated, "The Copyright Office believes that the application of GAAP will reduce the likelihood of unusually high reserves,

thereby minimizing the possibility for losses of earned interest." *Id.*

Currently, GAAP applies to several different provisions in the section 115 regulations adopted by the Copyright Royalty Judges. Their regulations state that GAAP should be applied to the calculations of service revenue. 37 CFR 385.11; *also see* proposed 37 CFR 385.21. Additionally, GAAP is applied to situations where the licensee calculates an applicable percentage based on offering type. 37 CFR 385.13(b) and (c); *also see, e.g.,* proposed 37 CFR 385.23(b). Finally in 37 CFR 201.19(f)(6)(ii) of the Office's regulations, GAAP is applied not only to the reserve calculation but also to the certification statement, which states that the auditing CPA will review the statements in accordance with GAAP.

In light of the history that GAAP has had in the administration of the compulsory license, the proposed regulations adopt this approach. The Copyright Office would like comments on whether to apply GAAP for the estimate of the public performance rights royalty calculation in the absence of an interim or final rate; and alternatively if GAAP is not the right approach, identification of an alternative methodology.

B. Application of Negative Reserve Balances in Calculating Payment Amounts

Under the existing Statement of Account regulations designed to address flat penny rates, licensees are permitted to account for negative reserve balances in calculating their royalty payments. By way of explanation, a negative reserve balance exists when physical phonorecords are returned to a compulsory licensee after the corresponding reserves for returns, and all other eligible reserves, have been eliminated. The result is that the compulsory licensee has paid royalties for the returned physical phonorecords and can include that amount as a credit in calculating the royalty payment for the current accounting period. While the Stakeholders agree that a licensee is permitted to establish reserves based only on its shipments of physical phonorecords, they disagree as to whether a compulsory licensee is and should be permitted to apply a negative reserve balance to future DPD distributions.

Copyright owners have stated that negative reserve balances only apply to physical phonorecords. In doing so, they have pointed out that the existing regulations specifically state that "[t]o the extent that the terms reserve, credit and return appear in this section, such